UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF LOUISIANA

IN RE: TAXOTERE (DOCETAXEL) PRODUCTS LIABILITY LITIGATION	)	**MDL No. 16-2740**
	)	**SECTION: "H" (5)**
This document relates to: Certain cases	)	

ORDER AND REASONS

Before the Court is a Motion for Summary Judgment on the Claims of Plaintiffs Whose Taxotere Treatment Started Before December 15, 2006 (Doc. 8977). The Court held oral argument on the Motion on May 7, 2020. For the following reasons, the Motion is **GRANTED IN PART** and **DEFERRED IN PART**.

BACKGROUND

Plaintiffs in this multidistrict litigation ("MDL") are suing several pharmaceutical companies that manufactured and/or distributed a chemotherapy drug, Taxotere or docetaxel,[1] that Plaintiffs were administered for the treatment of breast cancer or other forms of cancer. Plaintiffs allege that the drug caused permanent alopecia—in other words, permanent hair loss. Plaintiffs bring claims of failure to warn, negligent misrepresentation, fraudulent misrepresentation, and more. The first bellwether trial was held in September 2019, and the second is set for October 19, 2020.

The instant Motion relates to nearly 1400 Plaintiffs who took Taxotere before December 15, 2006. Defendants argue that Plaintiffs have no evidence to show that Defendants had a duty to warn before this date. Defendants point

[1] Docetaxel is the generic version of Taxotere.

to evidence from Plaintiffs' expert Dr. David Kessler, who testified that Defendants' duty to warn arose on December 15, 2006. Accordingly, Defendants move for summary judgment against these select Plaintiffs.

LEGAL STANDARD

Summary judgment is warranted where "there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law."[2] A genuine issue of fact exists only "if the evidence is such that a reasonable jury could return a verdict for the nonmoving party."[3] Rule 56 of the Federal Rules of Civil Procedure "mandates the entry of summary judgment, after adequate time for discovery and upon motion, against a party who fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial."[4] "If the evidence is merely colorable, or is not significantly probative, summary judgment may be granted."[5]

LAW AND ANALYSIS

I. The Parties' Arguments

Defendants argue that the Plaintiffs at issue cannot create a genuine dispute of material fact on an essential element of their claims. Specifically, Defendants aver that the Plaintiffs have no evidence to show that at the time of their treatment, Defendants had a duty to warn them of Taxotere's risk of permanent alopecia. Indeed, in connection with the first bellwether trial,

[2] FED. R. CIV. P. 56.
[3] Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986).
[4] Celotex Corp. v. Catrett, 477 U.S. 317, 322 (1986).
[5] *Anderson*, 477 U.S. at 249–50 (internal citations omitted).

Plaintiffs' regulatory and label expert, Dr. David Kessler, testified that the Defendants' duty was triggered on December 15, 2006. On that date, a doctor by the name of Scot Sedlacek gave a presentation at a "major breast [cancer] conference."[6] Dr. Sedlacek discussed the link between Taxotere and permanent chemotherapy-induced alopecia.[7]

In response, Plaintiffs ask the Court to disregard the testimony from Dr. Kessler. Plaintiffs aver that his testimony was case specific and should not be considered in connection with this Motion. Plaintiffs note that in his report, Dr. Kessler specified that his opinions were tailored to three certain bellwether Plaintiffs and their respective dates of Taxotere administration. He wrote that he "reserve[d] the right to study the issues at both earlier and later dates."[8] In addition to this, Plaintiffs argue that there is an issue of fact regarding when Sanofi acquired knowledge of the risk of permanent alopecia associated with Taxotere. Plaintiffs argue that based on the evidence, Sanofi had knowledge before December 15, 2006, thereby triggering a duty to warn before this date. Lastly, Plaintiffs emphasize that dozens of state laws are at issue, and these laws do not use one monolithic standard for "knowledge." Because of this, Plaintiffs argue that the Court would have to undertake a Herculean effort in deciding whether summary judgment is appropriate in each jurisdiction.

II. Authority of MDL Courts

An MDL court has the authority to enter dispositive orders terminating cases transferred under 28 U.S.C. § 1407.[9] Transferee courts may consider the

[6] Doc. 8977-2 at 8 (quoting Dr. Kessler deposition).
[7] *See* Doc. 8977-5 at 81 (referring to Dr. Sedlacek as "the author of a 2006 study finding that 6.3% of patients experienced irreversible alopecia with Taxotere").
[8] Doc. 9231 at 4.
[9] In re Donald J. Trump Casino Sec. Litig., 7 F.3d 357, 364–68 (3rd Cir.1993), *cert. denied*, 510 U.S. 1178 (1994).

laws of multiple states and decide whether summary judgment is warranted against certain plaintiffs.[10] Indeed, MDL courts often rule on omnibus motions involving issues common to many cases.[11] The roughly 1400 cases at issue were filed directly into this MDL, and the Court will treat these cases "as if they were transferred from a judicial district sitting in the state where the case originated."[12] Accordingly, the law that applies in each case will be the law of the state where the case originated, which is the state where a Plaintiff was prescribed or administered her Taxotere treatment.[13]

III. Analysis

This Court agrees with Plaintiffs that this Motion presents a difficult task given that each jurisdiction has its own analysis for determining whether a manufacturer had a duty to warn. For example, as Sanofi highlights in its chart setting forth these laws, D.C. holds a manufacturer liable for any injury that was "foreseeable," [14] whereas New Hampshire law considers what

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[10] *See* In re TMJ Implants Prods. Liab. Litig., 872 F. Supp. 1019, 1024 (D. Minn. 1995) (explaining that the transferor court "has considered the law of each of the states that would apply in the individual actions" in products liability MDL and entering summary judgment in two defendants' favor).

[11] In re Lipitor (Atorvastatin Calcium) Mktg., Sales Practices & Prods. Liab. Litig., 227 F. Supp. 3d 452, 490 (D.S.C. 2017).

[12] In re Depuy Orthopaedics, Inc., 870 F.3d 345, 348 (5th Cir. 2017) (quoting In re Yasmin & Yaz (Drospirenone) Mktg., Sales Practices & Prods. Liab. Litig., No. 3:09–md–02100, 2011 WL 1375011, at *6 (S.D. Ill. Apr. 12, 2011)); Wahl v. Gen. Elec. Co., 786 F.3d 491, 496 (6th Cir. 2015) ("[T]he weight of authority has adopted Yasmin's rule"). *See also* Pretrial Order No. 4 (Rec. Doc. 122) ("[Direct filing] will have no impact on choice of law that otherwise would apply to an individual case had it been originally filed in another district court and transferred to this Court pursuant to 28 U.S.C. § 1407.").

[13] *See Yasmin*, No. 3:09–md–02100, 2011 WL 1375011, at *6 ("[T]he Court considers the originating state to be the state where the plaintiff purchased and was prescribed the subject drug"); In re Avandia Mktg., Sales Prac. & Prods. Liab. Litig., No. 3:09–md–02100, 2012 WL 3205620, at *2 (E.D. Pa. Aug. 7, 2012) (explaining that direct-filed cases "should be governed by the law of the states where Plaintiffs received treatment and prescriptions for Avandia").

[14] Doc. 8977-4 at 3 (quoting Payne v. Soft Sheen Prod., Inc., 486 A.2d 712, 722 n.8 (D.D.C. 1985)).

knowledge a manufacturer "should have acquired" and what tests it "should have conducted." [15] As another example, Idaho law provides that manufacturers are "held to the knowledge and experience of experts in their fields," so the question is not merely what the seller knew but what information was available at the time of distribution of the product. [16]

To make this task more manageable, the Court has focused on Louisiana law for now and will defer ruling on any other jurisdictions. Under Louisiana law, a manufacturer has a duty to update warnings as new information about the risks of a product is discovered. [17] The statute provides as follows:

> A manufacturer of a product who, after the product has left his control, acquires knowledge of a characteristic of the product that may cause damage and the danger of such characteristic, or who would have acquired such knowledge had he acted as a reasonably prudent manufacturer, is liable for damage caused by his subsequent failure to use reasonable care to provide an adequate warning of such characteristic and its danger to users and handlers of the product. [18]

As the Fifth Circuit has explained, the "duty to warn a particular plaintiff is measured by the state of scientific and/or technical knowledge at the time the product left the manufacturer's control." [19] The law states as follows:

> [A] manufacturer of a product shall not be liable for damage proximately caused by a characteristic of the product if the manufacturer proves that, at the time the product left his control, he did not know and, in light of then-existing reasonably available scientific

[15] *Id.* at 6 (quoting Cheshire Med. Ctr. v. W.R. Grace & Co., 853 F. Supp. 564, 570 (D.N.H. 1994), *aff'd*, 49 F.3d 26 (1st Cir. 1995)).
[16] *Id.* (quoting Toner v. Lederle Labs., 732 P.2d 297, 307 (Idaho 1987)).
[17] Stahl v. Novartis Pharm. Corp., 283 F.3d 254, 272 n.11 (5th Cir. 2002).
[18] LA. REV. STAT. ANN. § 9:2800.57(C)
[19] *Stahl*, 283 F.3d at 272 n.11.

> and technological knowledge, could not have known of the characteristic that caused the damage or the danger of such characteristic.[20]

To defeat summary judgment on a failure to warn claim, "a plaintiff must demonstrate specific facts in the record that a warning is inadequate."[21] As the Fifth Circuit has noted, "the precise question [is] not whether the defendant failed to warn the plaintiff . . . , but rather whether the plaintiff presented proper evidence that the [products] have potentially damage-causing characteristics and whether the defendant failed to use 'reasonable care to provide an adequate warning.'"[22] A plaintiff should present evidence as to the cause, frequency, severity, or consequence of any damage-causing characteristic.[23] "Without a proper understanding of the . . . damage-causing characteristics, the scope of any duty to warn is unclear."[24] A tenuous conclusion from an expert is insufficient to create an issue of fact as to whether the language used in a drug label was inadequate.[25]

Plaintiffs have failed to create an issue of fact regarding whether Defendants, under Louisiana law, had a duty to warn prior to December 15, 2006. Plaintiffs' own expert testified that Defendants' duty arose on this date. Dr. Kessler testified that Sanofi's duty to warn arose "not later than about 2009 and probably as early as around 2006."[26] According to Dr. Kessler, Dr.

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[20] LA. REV. STAT. ANN. § 9:2800.59(B).
[21] Guillory v. Pellerin, No. 2:07 CV 1683, 2009 WL 922474, at *4 (W.D. La. March 31, 2009) (citing *Stahl*, 283 F.3d at 264).
[22] *Id.* (citing Grenier v. Med. Eng'g Corp., 243 F.3d 200, 205 (5th Cir.2001)).
[23] *See id. See also Grenier*, 243 F.3d at 205.
[24] *See Guillory*, 2009 WL 922474, at *4. *See also Grenier*, 243 F.3d at 205.
[25] *Stahl*, 283 F.3d 254 at 271–72 (rejecting expert testimony on label instructions, finding testimony equivocal, ill-supported, and "simply insufficient to preclude summary judgment" on failure to warn claim).
[26] Doc. 8977-2 at 8.

Sedlacek's presentation on December 15, 2006 is "a pretty good cutoff."[27] On this date, Dr. Sedlacek was able to show a statistically significant association between Taxotere and permanent alopecia, and after this, according to Dr. Kessler, "the bells should be going off" for Sanofi.[28]

Plaintiffs' main argument is that Dr. Kessler's testimony was case specific and should not be considered in connection with this Motion. Plaintiffs write that "Dr. Kessler has never offered an opinion for any Plaintiff in this MDL who was administered Taxotere before December 15, 2006."[29] These assertions fall flat. For months now, the parties and this Court have discussed the filing of this "fencepost" (or omnibus) motion. The parties agreed on the briefing schedule. Plaintiffs had ample time and opportunity to identify and present expert evidence disputing the damaging testimony from Dr. Kessler. Yet Plaintiffs failed to do so.

Plaintiffs point to scant evidence to rebut Dr. Kessler's opinion on the extent of Sanofi's knowledge, an issue on which Plaintiffs carry the burden of proof. Notably, Plaintiffs do not present the Court with additional expert evidence. Plaintiffs aver that their expert, Dr. David Madigan, analyzed certain data from Sanofi's clinical trials and noticed increases in the rates of permanent alopecia in 2004 and 2005, but the Court was unable to locate the cited expert report in the record. In search of a stronger, more specific opinion, the Court studied Dr. Madigan's report from the September trial of Barbara Earnest. The Court found only his tenuous conclusion that "adequate statistical evidence supporting a causal association between Taxotere (docetaxel) and permanent/irreversible alopecia was available to Sanofi several

[27] *Id.*
[28] *See id.*
[29] Doc. 9231 at 1.

years earlier [than 2015]." [30] Rather than provide the Court with an unequivocal expert opinion that creates an issue of fact on the scope of Defendants' duty to warn, Plaintiffs point the Court only to equivocal evidence in the record, all of which leaves the Court guessing.

Plaintiffs emphasize that Sanofi internally discussed Dr. Sedlacek's research, but Plaintiffs fail to show that these communications occurred before December 15, 2006. Instead, Plaintiffs state that they occurred "around the time of [Dr. Sedlacek's] publication."[31] The Court reviewed the documents at issue and was unable to identify the date that the communications were transmitted. [32] Even if the communications occurred before Sedlacek's presentation, the Court is not convinced that the communications alone establish knowledge under Louisiana law. In the email Plaintiffs cite, the Sanofi representative does not delve into the specifics of Sedlacek's research. The email reports that Sedlacek is no longer using a certain regimen and that "[t]he excuse of permanent alopecia is a concern of his."[33] The representative does not give credit to Sedlacek's findings but instead states that "[S]edlacek even mentioned that he had limited experience in that area."[34] Without more, this correspondence is not enough to rebut Dr. Kessler's testimony.

Plaintiffs argue that other evidence shows Sanofi's knowledge before 2006. Plaintiffs aver that Sanofi received the same information upon which Dr. Sedlacek based his research. Plaintiffs explain that Sanofi received "Adverse Event Reports" from Dr. Sedlacek's nurse in July and October 2005. Without expert evidence, however, the Court cannot say that a reasonably prudent

[30] Doc. 6144-1 (p. 20).
[31] Doc. 9231 at 6.
[32] *See* Doc. 9231-38.
[33] Doc. 9231.
[34] *Id.*

manufacturer should have drawn certain conclusions from this data and effectively acquired knowledge that Taxotere is causing permanent hair loss. Indeed, Dr. Sedlacek himself narrowly qualified his findings, reporting only that "when docetaxel is administered after 4 doses of AC, there is a small but significant possibility of poor hair regrowth lasting up to 7 years."[35]

Plaintiffs point to other reports that Sanofi received from Dr. John Mackey. Plaintiffs aver that Dr. Mackey reported at least fifteen cases of permanent hair loss between 2003 and 2004. Plaintiffs, however, admit, that the exact number of patients Dr. Mackey considered is unknown.[36] Plaintiffs also do not establish whether alternative causes of hair loss were considered with respect to these fifteen cases. For example, the Court is unclear on how many rounds of chemotherapy these patients received. The Court is also unclear on whether these patients received Taxotere to treat metastatic breast cancer or whether these patients received Taxotere in the adjuvant setting. Without more context, the Court cannot make such a leap to say that these fifteen reports should have led Sanofi to conclude that Taxotere was causing permanent hair loss. The Court further notes that Plaintiffs point only to reports from Dr. Sedlacek and Dr. Mackey, but there is no evidence of how many doctors were prescribing Taxotere during the years at issue.

Ultimately, Plaintiffs have failed to come forward with reliable evidence that clarifies or disputes Dr. Kessler's testimony. Considering Louisiana law, Plaintiffs have not created an issue of fact on whether a reasonably prudent manufacturer would have drawn certain conclusions before December 15, 2006, thereby triggering Sanofi's duty to warn. Therefore, the Court concludes that summary judgment is warranted under Louisiana law.

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[35] Doc. 9231.
[36] Doc. 9231 at 11.

For the other jurisdictions at issue, the parties are instructed to jointly submit to the Court a chart that groups jurisdictions by use of the same language in defining the standard for "knowledge." The Court will then consider the submission and issue rulings as to each group of jurisdictions. If any further briefing is necessary, the Court will alert the parties.

CONCLUSION

For the foregoing reasons, the Motion for Summary Judgment on the Claims of Plaintiffs Whose Taxotere Treatment Started Before December 15, 2006 (Doc. 8977) is **GRANTED IN PART** and **DEFERRED IN PART**. The parties should jointly submit to the Court a list of the Louisiana cases that can be dismissed pursuant to this order;

IT IS FURTHER ORDERED that the parties should jointly submit to the Court the chart described herein no later June 19, 2020.

New Orleans, Louisiana this 1st day of June, 2020.

JANE TRICHE MILAZZO
UNITED STATES DISTRICT JUDGE